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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/932,227	09/17/1997	ERIC T. FOSSEL	S1509.70029US00	5092

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EXAMINER	
MULLIS, JEFFREY C	
ART UNIT	PAPER NUMBER
1796	
MAIL DATE	DELIVERY MODE
01/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/932,227	FOSSEL, ERIC T.	
	Examiner	Art Unit	
	Jeffrey C. Mullis	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-35,38-44,47-50,56-59,61-63,70 and 72-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35,38-44,47-50,56-59,61-63,70 and 72-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-14-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 33-35, 38-44, 47-50, 56-59, 61-63, 70 and 72-77 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative for the full scope of the claims and therefore lacks utility. Note Hirvonen et al., newly cited who disclose that experiments attempting to transfer solatol with human cadaver skin while varying sodium chloride concentration were unsuccessful in enhancing delivery and that "(I)n view of the present results, it is unlikely that the diffusion potential would be worth using as an enhancement method for transdermal drug delivery" (note the abstract as well as the paragraph bridging the columns on page 38). In view of the disclosure of Hirvonen those skilled in the art would therefore question weather agents for creating a hostile biophysical environment (such as are disclosed by applicants to include salts such as sodium chloride) would cause the L-arginine (derivative) of the claims to migrate from the delivery vehicle to the skin (including the penis) as claimed with the exception of use of specifically arginine with the salts used in the concentrations of applicants declaration of 10-14-08.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-35, 38-44, 47-50, 56-59, 61-63, 70 and 72-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the full scope of the invention. In view of the disclosure of Hirvonen, cited above, those skilled in the art would question weather agents for creating a hostile biophysical environment (such as are disclosed by applicants to include salts such as sodium chloride) would cause the L-arginine (derivative) of the claims to migrate from the delivery vehicle to the skin (including the penis) as claimed and applicants method using L-arginine derivatives in which agents for creating a hostile biophysical environment (such as are disclosed by applicants to include salts such as sodium chloride) cause the L-arginine (derivative) of the claims to migrate from the delivery vehicle to the skin (including the penis) as claimed does not appear to be enabled except for the specific combination of agents and high concentrations and arginine per se of applicants declaration.

Claims 50 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 59 ultimately depend from cancelled claims and are therefore unclear.

The declaration under 37 CFR 1.132 filed 10-14-08 is insufficient to overcome the rejection of claims 33-35, 38-44, 47-50, 56-59, 61-63, 70 and 72-77 as set forth in the last Office action because: Firstly, Hirvonen discloses that different mechanisms act to defeat enhancement of transdermal drug delivery at high and low electrolyte concentrations and for this reason alone applicants declaration is insufficient to show

enablement of the claimed method at low salt concentration. Secondly, Hirvonen provides a detailed theoretical discussion as to why in general enhancement of transdermal drug delivery by added electrolytes should fail and for this reason it must be assumed that in general such enhancement should fail and that any enhancement encountered should therefore pertain only to the specific drug (in the instant case arginine as such), electrolyte and concentrations thereof used. Lastly, Seguin, newly cited by applicants indicates that nonpolar derivatives of arginine readily penetrate the epidermis (last paragraph in column 3). This is in disagreement with applicants declaration and applicants entire genus of arginine and derivatives thereof do not appear to share common properties with regard to penetration of the epidermis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33 and 61 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ennen (WO 95/15147).

Patentees disclose compositions for application to the “epidermis” (second paragraph on page 1) containing Ornithine (encompassing applicants arginine

derivatives) or arginine hydrochloride (encompassing applicants arginine derivative or salt) as well as sodium and ammonium salts (abstract and the second paragraph on page 4 as well as the examples). The composition may be in the form of an emulsion (page 1, lines 7-9) and include lipids such as would reasonably appear to result in liposomes. Since the salts are present at at least the lowest level recited by the claims for creating a hostile biophysical environment the hostile biophysical environment characteristic would reasonably appear to be inherent.

Product-by-process claims are not rejected using the approach set out in Graham v. Deere. It is applicant's burden to show that there is a non-obvious difference between the product of a product-by-process claim and a prior art product which reasonably appears to be the same or only slightly different whether or not the prior art product is produced in the same manner as the claimed product. Note In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972) and In re Thorpe, 227 USPQ 964 (CAFC 1985) in this regard.

Applicant's arguments filed 10-14-08 have been fully considered but they are not persuasive. The defects in applicants declaration are set out above. Hirvonen considered the use of cadaver skin to be relevant to live tissue as there is otherwise no use for a process in which drugs are diffused into dead tissue. The administration of

drugs is only of use to living organisms. The examiner is aware of serial number 10/201635 reviewed its prosecution prior to the previous Office action.

The Office action of 4-23-08 was indeed non final.

Any inquiry concerning this communication should be directed to Jeffrey C. Mullis at telephone number 571 272 1075, M-F, 9-5pm.

Jeffrey C. Mullis
Primary Examiner
Art Unit 1796

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/Jeffrey C. Mullis/

Primary Examiner, Art Unit 1796